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TFW 1617 #11

Attorney's Docket No.: 06275-150003 / D 1841-3P US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Carl-Axel Bauer *et al.* Art Unit : 1617
Serial No. : 10/010,283 Examiner : Jennifer M. Kim
Filed : November 13, 2001
Title : NEW USE FOR BUDESONIDE AND FORMOTEROL

**MAIL STOP AMENDMENT**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. References CC and CD on the attached form are identical to references BR and BS, respectively, on the PTO-1449 submitted November 4, 2005. They are cited again on the attached PTO-1449 to clarify the page numbers included with those references. References CC and CD are not included with this submission as they are identical to the previously submitted BR and BS.

Five references cited on the Form PTO-1449 submitted November 4, 2005 (references BD, BQ, BR, BS, and BT), are non-English references. All five references were cited in opposition proceedings filed against a counterpart European patent. As required under 37 CFR § 1.98(a)(3), a concise explanation of the relevance of each of these documents is provided below. The statements below are essentially the same characterizations provided by the opponents in the proceedings. English language translations of the documents are not readily available but can be obtained should the Examiner request them.

**Reference BD**: "*Atemstillstand*" *Pschyrembel Klinisches Wörtebuch* (2002) (in German):

This reference categorizes chronic bronchitis and emphysema as obstructive pulmonary diseases.



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**Reference BQ**: "FORADIL" *Compendium Suisse des Medicaments*, Supplement 1a pages 7-8 (1991), and **Reference BT**: "FORADIL" Patient information leaflet, published by IKS, Switzerland (12/1990) (both in French):

These two references each disclose that FORADIL® is a bronchodilator pressurized aerosol composition having as its sole active ingredient formoterol fumarate dihydrate, delivering 12 μg per puff. FORADIL is characterized as having a rapid and long duration bronchodilator effect (up to 12 hours) which permits, in general, a twice daily use of the medicament. Under the heading "*Posologie*" ("Dosages") at page 7, right-hand column, reference BQ discloses that in general the medicament is taken as one puff, twice a day, preferably morning and evening. Under the heading "*Indications/Possibilités d'emploi*" ("Indications/Uses") also at page 7, right-hand column, reference BQ as translated reads: "Treatment and prophylaxis of dyspnoea in reversible obstructive airways disease, such as asthma and chronic bronchitis accompanied by bronchoconstriction—with or without emphysema." Reference BT, under the heading "What is Foradil and for what is it used?" in the left-hand column, discloses that FORADIL is indicated for use in the treatment of bronchitis.

**Reference BR**: *Compendium Suisse des Medicaments*, 15th Ed. 1997/1998, Ed. Grand Public, compiled June 1996, pages 2-3, 419-420, 866 (in French):

This reference is from the collection of information leaflets (called "datasheets" below, under the description of reference BS) that are packed with medicaments supplied in Switzerland. The first paragraph at the top of page 3 is translated as follows:

> The Swiss benefit from an advantage which is the envy of other nations: that of finding in each pack of medicaments a leaflet with detailed, clear and comprehensible information. The text of these leaflets is in effect put in the hands of all and is structured in a way that corresponds to the needs of the patient. Under their current standardised form, these packaging leaflets are the admiration of Europe.

These leaflets have been produced since 1989.

The patient information leaflet for FORADIL aerosol doseur (aerosol dispenser) begins at the top of the middle column at page 419. This leaflet was last updated in December 1993.

Under the heading "*Composition*" in the right-hand column, the text as translated by the opposer reads: "Foradil contains formoterol fumarate (active substance), 12 micrograms per aerosol puff, CFC propellant gas, 99% (v/v)."

Under the heading "*Propriétés/Emploi thérapeutique: Qu'est-ce que le Foradil et quand est-il utilisé?*" ("What is Foradil and for what is it used?"), in the middle column, the text as translated reads: "FORADIL treats asthma and facilitates breathing. It dilates the bronchi in the case of asthma, bronchitis and other respiratory diseases, as well as asthma caused by irritant substances, exercise or cold air."

The patient information leaflet for FORADIL poudre (powder) begins at the bottom of the right-hand column at page 419. The text was last updated in June 1996. According to the leaflet, under the heading "*Composition,*" at page 420 in the right-hand column, the text as translated reads: "1 capsule contains 12 µg formoterol fumarate as well as lactose."

The uses for FORADIL poudre are essentially the same as those described above for FORADIL aerosol doseur.

The patient information leaflets for PULMICORT® aerosol doseur and PULMICORT® Turbuhaler/Respules are at page 866. These leaflets were last updated in June 1993. The aerosol doseur product is described in the leaflet under the heading "*Composition,*" in the right-hand column, as follows: "1 inhalation of PULMICORT aerosol inhaler contains 200 µg budesonide and, as excipient, a CFC propellant gas, 99% (v/v)."

Under the heading "*Propriétés/Emploi thérapeutique: Qu'est-ce que Pulmicort et quand est-il utilisé?*" ("What is Pulmicort and for what is it used?"), in the middle column, the text as translated reads: "Pulmicort contains the synthetic active ingredient budesonide as active ingredient. This has an anti-inflammatory effect for the treatment of respiratory tract diseases such as asthma and chronic bronchitis."

**Reference BS**: *Compendium Suisse des Medicaments*, 18th Ed. 1997, compiled June 1996, pages 5, 849-851 and 1635-1636 (in French):

This reference includes datasheets (called "leaflets" above, under the description of reference BR) for both FORADIL (pages 849-851) and PULMICORT (pages 1635-1636). At page 850, under the heading "*Indications/Possibilités d'emploi,*" in the right-hand column, the

indications include (as translated) "prophylaxis and treatment of bronchoconstriction in reversible obstructive airways disease such as bronchial asthma and chronic bronchitis, with or without emphysema," which are essentially the same as those listed in the 1990 datasheet. However, the association with inhaled steroid treatment is strengthened. Under the heading "*Posologie/Mode d'emploi*" at the bottom of page 850, in the right-hand column, the datasheet as translated reads: "It is recommended to prescribe an anti-inflammatory (inhaled steroid, oral route) in parallel with the long term administration of long acting ß2-stimulants."

The datasheet for PULMICORT, beginning at page 1635, was updated in May 1992. Under the heading "*Indications/Possibilities d'emploi*," the indications given for budesonide are: "Reversible obstructive airways disease, such as bronchial ashma and chronic obstructive bronchitis in the course of which corticoid therapy is indicated."

This reference also discloses that dosing for both FORADIL and PULMICORT was generally accepted to be twice per day. For example, at page 851, in the top left-hand column, under the headings "*Traitement d'entretien et prophylaxie*" ("Maintenance Therapy and Prophylaxis") and "*Adultes, y compris patients âgés*" ("Adults, including aged patients"), FORADIL treatment is described as follows: "In general, 1 capsule of powder for inhalation, 2 times per day, preferably morning and evening." Similarly, at page 1635, in the right-hand column, under the heading "*Posologie usuelle*" ("Usual dosages"), PULMICORT treatment is described as follows: "Pulmicort should be used before meals or after rinsing the mouth. Dosing of Pulmicort is flexible. One administration, twice a day is, as a rule, sufficient."

This statement is being filed after a first Office action on the merits, but before receipt of a final Office action or a Notice of Allowance. A check for $180 in payment of the late submission fee of §1.17(p) is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 06275-150003.

Respectfully submitted,

Date: January 10, 2006

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